

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC. CIVIL ACTION NUMBER:
and SEBELA US INC.,

23-cv-2853-CPO

Plaintiffs,

MARKMAN HEARING

v.

**LUPIN LIMITED and LUPIN
PHARMACEUTICALS, INC.,
Defendants.**

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
October 29, 2024
Commencing at 10:17 a.m.

B E F O R E: THE HONORABLE CHRISTINE P. O'HEARN,
UNITED STATES DISTRICT JUDGE

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Robert Raleigh, Client Representative
David Chavous, Client Representative
Anissa Davidson, Client Representative

1 (Proceedings held in open court before The Honorable
2 Christine P. O'Hearn, United States District Judge, at 10:17
3 a.m.)

4 THE COURTROOM DEPUTY: All rise.

5 THE COURT: Please be seated. Sorry to keep you
6 waiting, counsel.

7 We're on the record in the matter of Braintree
8 Laboratories vs. Lupin Limited, Docket 23-cv-2853.

9 Can I have appearances of counsel, starting with
10 plaintiffs.

11 MR. MILLER: Good morning, Your Honor. For the
12 plaintiffs, Keith Miller from Robinson Miller in Newark, New
13 Jersey. Also with me are co-counsel from Wilmer Hale, Lisa
14 Pirozzolo, Christopher Noyes, Lauren Matlock-Colangelo, and
15 Gabe Rosanio.

16 We also have client representatives in the back from
17 Braintree, Robert Raleigh, David Chavous, and Anissa Davidson.

18 THE COURT: Okay. Good morning. And for the
19 defendant?

20 MR. RICHTER: Good morning, Your Honor. James Richter
21 of Midlige Richter on behalf of the defendants. And with me
22 today from the Knobbe Martens firm are my co-counsel, William
23 Zimmerman and Brian Barnes.

24 THE COURT: Okay. Just give me one moment, counsel.

25 Okay. The first thing I want to go through is since

1 we were last here, before we start, there had been a
2 stipulation that was filed and then a letter that I received
3 yesterday, so I just want to go through the patents so I
4 understand and make sure I have the claims that are still at
5 issue just so we're all on the same page.

6 With respect to the '656 patent, the claims that I
7 have remaining at issue are 2, 4, 5, 6, 7, 12, 16, and 19. And
8 so the claims that are there I have, therefore, no longer at
9 issue are 1, 8, 9, 11, 17, 18, and 20.

10 Is that correct from everyone's perspective? Whoever
11 is going to speak on behalf of plaintiffs?

12 MS. PIROZZOLO: Your Honor, we believe Claim 1 is
13 still at issue.

14 THE COURT: Okay. Let me get your stipulation. I
15 just did this quickly this morning, so I could have been
16 mistaken.

17 So you believe it's 1, 2, 4, 5, 6, 7, 12, 16, and 19
18 still at issue?

19 MS. PIROZZOLO: That's correct, Your Honor.

20 THE COURT: Is that consistent, Mr. Richter? Whoever
21 is going to speak on behalf of defendants?

22 MR. RICHTER: Your Honor, I think my co-counsel are
23 currently confirming that.

24 THE COURT: Whoever is going to address that. I just
25 would like to make sure I understand exactly what the claims

1 are and exactly what we're all talking about.

2 MR. ZIMMERMAN: Your Honor, can you repeat that list
3 for the '656 patent, please?

4 THE COURT: What I initially said was I believe the
5 claims that are remaining are 2, 4, 5, 6, 7, 12, 16, and 19.
6 And the plaintiffs said that they also believe 1 is still at
7 issue.

8 MR. ZIMMERMAN: Yes, Your Honor.

9 THE COURT: Okay.

10 MR. ZIMMERMAN: Thank you.

11 THE COURT: You believe Claim 1 is at issue also?

12 MR. ZIMMERMAN: Yes.

13 THE COURT: And this is why I go through this with you
14 all.

15 With respect to patent '498, based on the letter
16 yesterday, I understand that I no longer need to construe the
17 term of "compromise" with respect to that patent; is that
18 correct?

19 MS. PIROZZOLO: That's correct.

20 THE COURT: Okay. So that eliminates a term that I
21 need to figure out what you all meant, right?

22 MS. PIROZZOLO: Yes, "comprising," right.

23 THE COURT: And so that means we are left with,
24 again -- and I could be incorrect, but this is my chicken
25 scratch this morning.

1 With respect to patent '498, the claims at issue are
2 2, 3, 5, 6, 7, 9, 10, 11, 12, and 13. Is that correct from
3 plaintiffs' perspective?

4 MR. NOYES: We're just confirming.

5 THE COURT: Take your time. Again, I just went
6 through your letter and then your stipulation and tried to...

7 MS. PIROZZOLO: Your Honor, we're trying to pull up
8 the stipulation. My apologies we did not --

9 THE COURT: That's okay. It's ECF 82. And I'm
10 looking at paragraph 2, which says: The submission of the ANDA
11 constitutes infringement of Claims 1, 4, and 8 if the claims
12 are not found invalid.

13 MR. ZIMMERMAN: Your Honor, am I correct that you're
14 listing the claims that are no longer at issue?

15 THE COURT: I'm listing the claims that I thought were
16 still at issue. So for '498, I have 2, 3, 5, 6, 7, 9, 10, 11,
17 12, and 13 as still being at issue.

18 You tell me the easiest way to do it. How would you
19 like me to do it?

20 For '656, originally the claims at issue are 1, 2, 3,
21 4, 5, 6, 7, 8, 9, 11, 12, 16, 17, 18, 19, and 20. Which claims
22 are no longer at issue? Can someone just tell me so I can
23 cross them off my list? Anyone who agrees?

24 MR. ZIMMERMAN: Your Honor, all of the claims other
25 than the ones listed in paragraph 1 of the stipulation that you

1 just read -- so all claims other than 1, 3, 8, 9, 11, 17, 18,
2 and 20. All the other ones go away.

3 THE COURT: Right, which is what I thought I said, but
4 perhaps I got them confused. All right. Hold on.

5 MR. NOYES: And if it would be easier, Your Honor, I
6 could just read into the record the claims that we agreed are
7 still at issue?

8 THE COURT: Can we do it that way? So for '656, what
9 are the claims that are still at issue, please?

10 MR. NOYES: So for the '656 patent, the claims at
11 issue that are subject to the infringement stipulation are
12 Claims 1, 3, 8, 9, 11, 17, 18, and 20.

13 THE COURT: So that's all I have to decide with
14 respect to that patent, right?

15 MR. NOYES: Correct, Your Honor.

16 THE COURT: Okay. With respect to '498.

17 MR. NOYES: With respect to the '498 patent, the
18 claims that remain at issue and are subject to the stipulation
19 of infringement are Claims 1, 4, and 8.

20 THE COURT: Okay. Which is a whole lot less.

21 (Laughter.)

22 MR. NOYES: Yes. We tried to narrow, Your Honor.

23 THE COURT: And I greatly appreciate when you do that.
24 Again, I was out yesterday, so I wanted to make sure I got this
25 right.

1 So for '864, the claims that are still at issue?

2 MR. NOYES: For the '864 patent, Your Honor, the
3 claims still at issue are Claims 1, 5, 9, and 10.

4 THE COURT: Again, a whole lot less.

5 MR. NOYES: Yes.

6 THE COURT: And for '697.

7 MR. NOYES: And for the '697 patent, Your Honor, the
8 claims still at issue are Claims 1, 4, 5, and 7.

9 THE COURT: Okay. Great.

10 Mr. Richter, do you agree? Or whoever is going to
11 speak, do you agree with that?

12 MR. ZIMMERMAN: Yes, Your Honor.

13 THE COURT: Okay. Perfect.

14 MR. NOYES: And, Your Honor, I think you'll hear
15 today, in that stipulation we've also agreed to further narrow
16 after expert discovery proceeds, so there will be further
17 narrowing in this case from the plaintiffs' perspective.

18 THE COURT: Okay. But for now that's where we are --

19 MR. NOYES: Yes, Your Honor.

20 THE COURT: -- so some of the issues in your briefing
21 are no longer relevant?

22 MR. NOYES: That's correct.

23 THE COURT: Particularly parts of your brief that
24 refer to construing the term "comprising of" as it related to
25 the '498 patent, that's completely off the table now?

1 MR. NOYES: That's correct.

2 THE COURT: Anything else that narrows what I need to
3 hear from you all or decide?

4 MS. PIROZZOLO: I don't believe so, Your Honor.

5 THE COURT: Okay. Just give me one second.

6 (Discussion held off the record.)

7 THE COURT: Okay. We talked about before that I like
8 to go term by term, so who would like to start and how would
9 you like to start from plaintiffs' perspective? I don't know
10 who's going to speak on behalf of whom.

11 MS. PIROZZOLO: Good morning, Your Honor, Lisa
12 Pirozzolo. I'll speak.

13 Mr. Noyes and I were going to divide up the argument
14 and I was going to address the issues with the preambles first.

15 THE COURT: Okay.

16 MS. PIROZZOLO: And then we'll proceed to the term
17 "consisting essentially of."

18 THE COURT: Okay. Just give me one second.

19 (Brief pause.)

20 THE COURT: Okay. I will hear from you, counsel.

21 MS. PIROZZOLO: Thank you, Your Honor. Lisa Pirozzolo
22 for Braintree.

23 Your Honor, I was going to start with a brief overview
24 of the asserted patents, then discuss claim construction
25 principles that apply throughout, and then address the disputed

1 terms.

2 The claim construction issues that the parties are
3 asking you to address today fall into two general buckets. The
4 first bucket concerns the issue of whether the preambles of the
5 claims are limiting and, if so, whether -- what the proper
6 construction of the term "colon cleansing" is.

7 The second bucket of claim construction issues is
8 construction of the term "consisting essentially of." And as I
9 mentioned, I'll address the preambles, and Mr. Noyes will
10 address "consisting essentially of."

11 THE COURT: Are you going to continue? Because my
12 screen is not showing here.

13 Is this supposed to be on, Haley?

14 THE COURTROOM DEPUTY: It should be.

15 THE COURT: It's not. Just because I can't quite see
16 as clearly as I would like to, so if we could get this one
17 working.

18 (Discussion held off the record.)

19 THE COURT: Go ahead. I am sorry, counsel.

20 MS. PIROZZOLO: So as a brief reminder, the four
21 asserted patents describe formulations and methods for colon
22 cleansing using three specific salts: Sodium sulfate,
23 magnesium sulfate, and potassium chloride in specified amounts.

24 The '656 and '697 patents have composition claims that
25 cover the solid oral formulation, and the '498 and '864 patents

1 have method claims that cover methods of administering the
2 formulation. In the parties' claim construction positions
3 focus on the independent claims of each of the patents, which
4 are Claim 1 of each of the patents.

5 So before diving into the specific issues, a few claim
6 construction principles that govern Braintree's positions. In
7 the leading case on claim construction, the *Phillips* case, the
8 federal circuit stated that claim terms are generally given
9 their ordinary and customary meaning, i.e., the meaning that
10 would be given to the term -- given to the term by a person of
11 ordinary skill in the art in the relevant field of the
12 invention.

13 Here, the field of the invention is defined in Column
14 1 of the specification as gastrointestinal diagnostic and
15 surgical procedures. And the background section in Column 1
16 goes on to discuss medical and diagnostic procedures on the
17 colon.

18 In *Phillips*, the federal circuit explained that
19 typically the most important consideration for claim
20 construction is intrinsic evidence. Intrinsic evidence
21 includes the claim language, the patent specification, and the
22 prosecution history. The court can also consider extrinsic
23 evidence such as testimony from expert witnesses or scientific
24 literature, but here neither party is relying on extrinsic
25 evidence for the construction of the claim terms at issue.

1 As to the three categories of intrinsic evidence,
2 *Phillips* explains that: The claims provides substantial
3 guidance to the meaning of particular claim terms; secondly,
4 the specification is also highly relevant and can be the single
5 best guide to the meaning of disputed terms; and finally, the
6 prosecution history can provide evidence of how the patent
7 office and the inventor understood the invention.

8 Today we'll go through the intrinsic evidence for the
9 disputed claim terms.

10 The claims at issue today have three different parts:
11 The preamble, noted here in yellow, is an introductory phrase
12 that summarizes the invention. The transition, in blue,
13 connects the preamble to the body of the claim and indicates
14 whether the claim is open, closed, or partially open to
15 additional elements.

16 In patent law, certain transition words have specific
17 legal meaning. For example, the word "comprising" is
18 open-ended and does not exclude additional unrecited elements.
19 So for example, here in Claim 1 of the '656 patent, the claimed
20 formulation must have the recited amounts of sodium sulfate,
21 magnesium sulfate, and potassium chloride, but it could have
22 other ingredients such as excipients.

23 The phrase "consisting of," on the other hand, is
24 closed. And this means that transition word would exclude
25 elements not listed in the claim.

1 The phrase "consisting essentially of" falls in the
2 middle. It allows additional unrecited elements that do not
3 materially affect the basic and novel characteristics of the
4 claimed invention, and Mr. Noyes will talk about that later.

5 The remainder of the claim shown in green is known as
6 the body of the claim.

7 Here, the parties dispute whether the preambles of the
8 four independent claims are limiting. I will talk about the
9 composition claims first and then discuss the method claims.

10 So in the composition claims, Claim 1 of the '656
11 patent and Claim 1 of the '697 patent share the same preamble,
12 a solid oral formulation for cleansing the colon of a subject,
13 so the issues for both of these claims are the same.

14 Slide 11 shows the parties' constructions of the
15 composition claim side by side. Braintree submits that the
16 preambles of the composition claims are limiting and should be
17 given their plain and ordinary meaning, which is a solid oral
18 formulation for cleansing the colon of a subject.

19 Lupin's proposal is to treat the preamble as
20 non-limiting. So under Lupin's proposed construction, the
21 claimed invention would not have to be a solid oral dosage form
22 and could be used for things other than colon cleansing. That
23 is utterly at odds with the intrinsic evidence in this case.

24 Lupin's alternative construction asks the Court to
25 divide up the preamble of the composition claims and find part

1 of it limiting and part of it not. This alternative proposal
2 is also at odds with the intrinsic evidence and the case law.

3 Before I get into the intrinsic evidence on the
4 composition claims, I would like to review the case law on when
5 preambles can be limiting. As the *Allen Engineering* case,
6 which Lupin relies on, makes clear whether a preamble is
7 limiting must be based "on the facts of each case in view of
8 the claimed invention as a whole."

9 Consistent with this, the federal circuit has held, as
10 it did in the *Bicon* case, that there is no litmus test for when
11 a preamble is limiting.

12 Preambles can generally be limiting in three
13 circumstances: Number one, when they recite essential
14 structure or steps; number two, if they provide antecedent
15 basis for terms in the body of the claim; number three, if
16 they're necessary to breed life and meaning into the claim.

17 And I'll talk about the case law discussing these
18 three situations now.

19 First, essential structure. As the federal circuit
20 noted in the *Proveris* case, a preamble is limiting when it
21 "recites essential structure or steps." Here, as we will
22 discuss, the term in the composition claims, "a solid oral
23 formulation for cleansing a colon of a subject," recites
24 essential structure.

25 And Courts in this district have found preambles like

1 this limiting. For example, in the *Purdue Pharma* case, which
2 we've cited in our brief, Judge Linares found a preamble
3 reciting "a solid unit dosage composition for the treatment in
4 MOTN insomnia" to be limiting, and he explained that the
5 preamble "set forth how the claimed dosage should be
6 structured, that is, a solid unit dosage."

7 Similarly, in the *Abbott Labs* case, Judge Cavanaugh
8 found that a preamble reciting a pharmaceutical composition in
9 the form of a molecular dispersion was a structural limitation
10 of the claim.

11 And in the *Helsinn* case before Judge Cooper, it was
12 found that a preamble specifying IV administration was a
13 structural limitation because it distinguished the claimed
14 invention from other forms, dosage forms such as intermuscular
15 or subcutaneous formulations.

16 The second situation in which a preamble is limiting
17 is when it provides antecedent basis for other limitations in
18 the body of the claim, as the federal circuit explained in the
19 *NTP* case.

20 For example, when he joined the federal circuit --
21 before he joined the federal circuit, Judge Stark in Delaware
22 found that a preamble reciting a method for reducing or
23 preventing or alleviating MS in a subject in need thereof was
24 limiting because it tied the preamble to the reference to the
25 subject in the body of the claim. And Judge Stark explained

1 that the preamble, thus, explained who was affected by the
2 claimed method and what the conditions were that were being
3 treated.

4 The third situation in which preamble can be limiting
5 is when it breeds life, meaning, and vitality into the claim,
6 as the federal circuit explained in the *Proveris* case, and this
7 is really a common sense principle. For example, in the
8 *Helsinn* case, which I've just mentioned, Judge Cooper was
9 talking about the IV administration, and the preamble stated
10 that the IV administration was to reduce the likelihood of
11 cancer chemotherapy-induced nausea. And Judge Cooper held that
12 that reference to "in order to reduce likelihood of cancer
13 chemotherapy-induced nausea" gave life and meaning to the claim
14 because the whole specification focused on treating this
15 particular condition and that was -- she found that was an
16 important aspect of the invention, and so the preamble was
17 limiting.

18 So applying these principles here to the composition
19 claims, the claims of the Braintree patents, the specification,
20 and the prosecution history make clear that the preambles of
21 the composition claims are limiting, and they're limiting under
22 any of the three principles that I just mentioned.

23 Number one, they recite essential structure; number
24 two, they provide antecedent basis for limitations in the
25 claims; and number three, they give life, meaning, and vitality

1 to the claims.

2 And I'll address these issues in the context of the
3 categories of intrinsic evidence that are most important. So
4 first I'll talk about the claims, then I'll talk about the
5 specification, and then I'll talk about the prosecution
6 history.

7 So in terms of the claims, the preambles of the
8 composition claims recite essential structure because they tell
9 you that the formulation for cleansing a colon must be solid
10 and must be orally administered to a subject. So the preamble
11 makes clear that the invention does not include other forms
12 such as liquids or injectables; it has to be a solid oral
13 dosage form.

14 And this rationale for finding the preamble limiting
15 is really the same as was at issue in *Purdue Pharma*, which was
16 a solid unit for treating insomnia; *Abbott Labs*, which was
17 molecular dispersion; and *Helsinn*, which was an IV for nausea.

18 The preambles of the claims are also limiting because
19 they provide antecedent basis for other limitations in the
20 claim. So the antecedent for the formulation, which is in
21 green, is in the preamble, which refers to a solid oral
22 formulation. And that was the rationale in the *Novartis* case
23 that I mentioned.

24 And finally, the preamble is also necessary here to
25 breed life and meaning into the claim. The preamble makes

1 clear that the claimed formulation is for colon cleansing,
2 which is a key aspect of the invention because colon cleansing
3 gives life and meaning to these claims, and it would be
4 improper to read colon cleansing out of these claims.

5 Like *Helsinn*, where Judge Cooper found that preventing
6 chemotherapy-induced nausea was a critical aspect of the
7 invention, it's very clear that a critical aspect of the
8 invention here is colon cleansing. That's what the entire
9 invention is about.

10 So I want to briefly address Lupin's argument that the
11 preambles don't recite essential structure. This is contrary
12 to the plain language of the claims, which make clear that the
13 formula's solid and orally administered.

14 In the *Abbott Labs* case where the court found the
15 preamble limiting because it recited essential structure is
16 useful here. It used a baking analogy which I'll adopt for
17 this case.

18 THE COURT: I like when judges use like very simple
19 things that non-scientist judges can understand. Totally get
20 it.

21 (Laughter.)

22 MS. PIROZZOLO: And it could be something else, but
23 here cookies and cakes were what was used. And just as the
24 recipe tells the baker to combine butter, flower and sugar, you
25 need to know whether you're making a cake or a cookie. And

1 here you have the ingredients of the formulation, but the
2 preamble is telling you you need to make it into a solid oral
3 dosage form, not a liquid form or an injectable.

4 So I'll move on to the specification, which as the
5 federal circuit taught in *Phillips*, is often the single best
6 guide to the meaning of claim terms. And we talked about this
7 a couple weeks ago, but there can be no serious doubt that the
8 specification of the patents emphasizes that the claimed
9 invention is a solid oral dosage form for colon cleansing.

10 All four patents have the same title which expressly
11 states this. The abstract confirms that the claim compositions
12 are oral solid dosage forms for colon cleansing. The
13 specification emphasizes that the solid oral tablet formulation
14 is a critical aspect of the invention. If you recall, the
15 background of the invention emphasizes that previous colon
16 cleansing products resulted in poor patient compliance because
17 patients had to drink large volumes of liquids. And the
18 background section also explained that while there had been
19 tablets before, they were phosphate-based and associated with
20 risks of renal failure and resulted in a black box warning from
21 FDA.

22 So the specification focuses on how the claimed
23 invention would address these shortcomings and address patient
24 compliance with a safe and effective solid oral dosage form.

25 And the detailed description of the invention makes

1 clear that the focus of the invention is on the use of tablets
2 for colon cleansing as an improvement over the prior art. In
3 total, the specification refers to solid oral formulations such
4 as tablets over 200 times, the colon nearly 70 times, and
5 cleansing of the colon and bowel over 50 times.

6 And consistent with Braintree's construction, the only
7 examples in the specification are three tablet formulations
8 which were tested to determine their suitability for colon
9 cleansing. In sum, the specification confirms repeatedly that
10 the solid oral formulation for colon cleansing is a key aspect
11 of the invention.

12 Going to the last category of intrinsic evidence, the
13 prosecution history further confirms that the preambles are
14 limiting. The excerpt on the left side of the slide is
15 Braintree's response to a rejection over a reference called
16 Bachwich. As the first sentence of this response to the office
17 action shows during -- in distinguishing Bachwich, Braintree
18 referred to its invention as formulating tablets that avoid
19 clinically significant electrolyte shifts and cleanse the
20 colon.

21 And as the left-hand part of the slide shows, this is
22 the examiner's statements for reasons of allowance of the
23 claimed invention, the '656 patent, and this shows that the
24 examiner also understood that the preamble of the claims were
25 limiting because, as we've highlighted here, in describing the

1 limitations of the claims, the examiner included the phrase
2 "solid oral formulation for cleansing a colon."

3 So if "solid oral formulation for cleansing a colon"
4 were not a limitation, as Lupin suggests, the examiner wouldn't
5 have called it a limitation in allowing the claims. The
6 prosecution history, therefore, demonstrates that the inventors
7 procured the patent based on the preamble being a limitation.
8 And in sum, all the evidence points to the preambles being
9 limiting.

10 So I'd like to now address Lupin's alternative
11 argument that the preambles of the composition claims should be
12 bifurcated so that a solid formulation is a limitation but for
13 cleansing the colon of the subject is not.

14 Lupin's proposal to bifurcate the preamble in this
15 manner is contrary to the intrinsic evidence and the case law.
16 Lupin cites two cases where courts have found a portion of the
17 preamble limiting, the *TomTom* and *Marrin* cases. In both of
18 those cases, the court found wording, certain wording that was
19 not part of the invention was, therefore, not limiting.

20 Here, the preamble does not contain wording that is
21 not part of the invention. As we discussed, the intrinsic
22 evidence makes clear that the essential -- the essence of the
23 invention is a tablet for colon cleansing.

24 And this case is like *Purdue Pharma* and *Helsinn*, both
25 of which included -- in *Purdue Pharma*, solid dosage to treat

1 insomnia; and in *Helsinn*, IV to treat nausea and vomiting
2 without parsing that preamble, as Lupin suggests should be done
3 here.

4 And in situations like this, the federal circuit has
5 declined to parse the preamble, for example, in the *SIMO*
6 *Holdings* case.

7 Lupin's construction is -- Lupin argues that under
8 *Catalina Marketing*, colon cleansing is merely a statement of
9 intended use and cannot be limiting unless Braintree relied on
10 it to distinguish the prior art.

11 So two responses. As I've just outlined, Braintree
12 did rely on colon cleansing to distinguish the prior art, and
13 the examiner did call the preamble a limitation of the claim.
14 But even if that were not the case, the *Eli Lilly* case --
15 Lupin's position is contrary to the *Eli Lilly* case on this
16 slide in which the federal circuit made clear that with respect
17 to apparatus or composition claims, a statement of intended
18 purpose can be limiting, whereas here it recites essential
19 structural elements and provides antecedent basis. So the *Eli*
20 *Lilly* case outlines principles that are directly applicable
21 here.

22 So unless Your Honor has any questions about the
23 composition claims, I could move on to the method claim.

24 THE COURT: I don't, not right now. Thank you.

25 MS. PIROZZOLO: As with the composition claims, the

1 preambles of the method claims are limiting and should be given
2 their plain and ordinary meaning. Lupin's contention that the
3 preambles are not limiting is contrary to the intrinsic
4 evidence in the case law. In addition, Lupin's proposed
5 alternative construction of some degree of colon cleansing
6 would inject ambiguity into the claims.

7 So the independent claims of the two method patents
8 have similar preambles. Claim 1 of the '498 patent, and it's
9 in yellow, is "a method of cleansing the colon"; and Claim 1 of
10 the '864 patent recites "a method of cleansing the colon of a
11 subject." The bodies of both claims confirm that they are
12 directed to methods of cleansing a colon.

13 For example, Steps A and C of Claim 1 of the '498
14 patent recite colon cleansing compositions, and Step D confirms
15 that the two doses of the colon cleansing compositions cleanse
16 the colon referenced in the preamble.

17 Similarly, Step H of the '864 patent, on the
18 right-hand side of the slide, states that it is the two doses
19 of the claim composition that cleanse the colon of the subject
20 recited in the preamble. So the same general principles of
21 claim construction that we have discussed already apply to the
22 method claims as well.

23 Moreover, as we have noted in our briefs, the federal
24 circuit has addressed the issue of whether preambles that
25 reference the intended purpose of a method are limiting. As I

1 mentioned, as stated in the *Eli Lilly* case, the federal circuit
2 has not hesitated to hold preambles limiting when they state an
3 intended purpose for methods of using a compound.

4 Similarly, in the *Boehringer* case, the federal circuit
5 held that this is because statements of purpose in a preamble
6 are not just circumstances in which the method might be useful.
7 Instead, they are reasons for the claim's existence. And that
8 is certainly true here with regard to colon cleansing.

9 So applying these principles to the method claims, the
10 method claims are limiting for two reasons. First, the
11 preambles make clear that the intended purpose of the claim
12 formulation is colon cleansing, as reflected in the
13 specification and the prosecution history.

14 Second, the phrase "method of cleansing a colon"
15 provides antecedent basis for claim limitations.

16 On the first point, the federal circuit has repeatedly
17 found preambles that recite the intended purpose of claim
18 methods to be limiting. We cited the *Lilly* case, which is a
19 method for treating a headache; the *Sanofi* case, which is a
20 method of increasing survival in a patient; and the *Jansen*
21 case, which is a method of treating or preventing anemia. So
22 these were all examples where statements of intended purpose
23 were found limiting in method claims.

24 The method claims are limiting for a second reason.
25 They provide antecedent basis to other limitations in the body

1 of the claim. "Cleansing the colon" of Claim 1 in the '498
2 patent provides antecedent basis for, we've highlighted in
3 green, "wherein the colon cleansing composition cleanses the
4 colon" in that claim.

5 Similarly, "cleansing the colon of a subject" in Claim
6 1 of the '864 patent provides antecedent basis for "cleanse the
7 colon of the subject" later in that claim, which is highlighted
8 in green.

9 And courts routinely find preambles limiting in these
10 instances where the preamble provides antecedent basis. That
11 is the *Novartis* case that I mentioned from Judge Stark.

12 Moving on to the specification, all of the support
13 that I mentioned before with regard to the composition claims
14 applies to the method claims as well, so I will not repeat it
15 here, but that includes the title of the patent, the abstract,
16 the repeated references to colon cleansing throughout the
17 specification.

18 Consistently, the specification describes the claimed
19 invention as a method for colon cleansing. And the prosecution
20 history similarly confirms that the patent applicant and
21 examiner understood that the method claims were limited to
22 methods of cleansing a colon of a subject.

23 In the upper excerpt on this slide, Braintree
24 distinguished the Bachwich reference because it disclosed a
25 colon cleansing method that used a different water regimen. So

1 they relied on colon cleansing to distinguish the Bachwich
2 reference.

3 And in the lower box, there's an excerpt from the file
4 history in which the examiner found that the prior art did not
5 disclose a colon cleansing method that involved the same steps
6 as the method of the '864 patent.

7 So the intrinsic evidence, in sum, confirms that the
8 preamble should be limiting in the method claims.

9 I would like to briefly address Lupin's proposal that
10 if the method claim preambles are limiting, the term "method of
11 cleansing the colon" should be construed as a method that may
12 result in some degree of cleansing a colon.

13 There is no reason to construe the term "colon
14 cleansing," which has a plain and ordinary meaning, and Lupin's
15 alternative construction would inject ambiguity into a claim
16 that is already clear.

17 So importantly, Lupin's construction is not tied to
18 any intrinsic evidence. The specification and the file history
19 do not ever use the phrase "may result in some degree of colon
20 cleansing." Instead, the specification makes clear in Column 1
21 that colon cleansing is performed to "permit adequate
22 visualization of the intestinal mucosa." Braintree's
23 construction, plain and ordinary meaning is consistent with
24 this.

25 Contrary to Lupin's suggestion, Braintree isn't asking

1 the Court to find that the methods need to result in some
2 particular degree of colon cleansing; rather, Braintree's
3 construction requires only that the methods be performed for
4 colon cleansing as opposed to for some other purpose that is
5 not colon cleansing.

6 THE COURT: Like, you're not asking me to construe
7 like, for example, when you have the cases where the issue is,
8 you know, less than certain percent and people say, well, I
9 have zero. So zero versus less than and what does that
10 really -- that's not encompassed in that. You're just saying
11 this is the purpose.

12 MS. PIROZZOLO: Yes, this is colon cleansing, not
13 fixing constipation or something like that.

14 THE COURT: Not some other purpose, right. But you're
15 not even focused on whatever degree that may result. Because,
16 quite frankly, given the way it's administered and depending
17 upon compliance and depending upon all of those other factors
18 that vary from each person, I don't know how you could even
19 guarantee that, right, or even estimate it?

20 MS. PIROZZOLO: That's correct.

21 THE COURT: So to me, that's the biggest -- I wanted
22 you to confirm that because I'm not sure how you could even
23 logistically or scientifically, whatever the right word is, do
24 that, say to some degree. Like, what is the value of that? To
25 you, does that have any value to add those terms?

1 And I'm assuming you're saying no, it has --

2 MS. PIROZZOLO: Plain meaning, colon cleansing. No
3 degree.

4 THE COURT: Has no value. Okay.

5 MS. PIROZZOLO: No degree.

6 And I'll just really end with the fact that in
7 addition to nothing supported by intrinsic evidence and the
8 points we just discussed, Lupin's construction is analogous to
9 the types of constructions the courts have rejected in other
10 cases.

11 So for example, in *Rensselaer Polytechnic*, the
12 defendant sought to construe aqueous solution as a solution
13 where the water is the main solvent, and the courts rejected
14 that construction because it said there was no -- the defendant
15 didn't specify any measure or threshold to determining how a
16 solvent would be determined to be the main solvent or not.

17 Similarly, in *Allen Engineering*, which Lupin relies
18 on, the court declined to find "fast steering" in a preamble
19 limiting because it was a relative term with no interpretive
20 frame of reference. So for those reasons as well, Lupin's
21 proposed construction should be rejected.

22 So if the Court doesn't have any questions on the
23 preamble, I will yield to opposing counsel.

24 THE COURT: I don't have any right now. Thank you.

25 MR. ZIMMERMAN: May I proceed, Your Honor?

1 THE COURT: One second, counsel.

2 (Brief pause.)

3 THE COURT: Okay.

4 MR. ZIMMERMAN: Thank you. Bill Zimmerman of Knobbe
5 Martens on behalf of the Lupin defendants. And I'll begin
6 first with the preamble terms.

7 If we could go to Slide 14, there are really two
8 disputed issues with respect to the preamble term. The first
9 is, should the preambles be construed as limitations, and if
10 that threshold answer is yes, what is the correct construction
11 of those terms?

12 If we could go to Slide 15.

13 The general rule with respect to preambles was set
14 forth in the federal circuit's *Allen Engineering* case, and it's
15 a longstanding rule, "generally, the preamble does not limit
16 the claims." That is the default.

17 THE COURT: I am sorry, where did you go back to? Are
18 you starting on Slide 14 and going forward?

19 MR. ZIMMERMAN: Yes.

20 THE COURT: Okay.

21 MR. ZIMMERMAN: We had started with the "consisting
22 essentially of" term, and when plaintiffs started --

23 THE COURT: That's okay. Thank you.

24 MR. ZIMMERMAN: And as we see from the *Catalina*
25 *Marketing* case: A preamble is generally not limiting when the

1 claim body describes a structurally complete invention such
2 that you could delete the preamble phrase and not affect the
3 structure or steps of the claim.

4 Now, if we turn to Slide 16, the federal circuit has
5 not given any bright-line rule with respect to preambles and
6 when they are and aren't limiting, but they've given guide
7 posts in various cases. So a preamble can be limiting when it
8 "recites essential structure or steps" that are "necessary to
9 give life, meaning and vitality to the claim." And it's not
10 just giving vitality to the claim, it's got to recite structure
11 or steps.

12 The second is when it's essential to understanding
13 terms or limitations that are recited later in the body of the
14 claim, or when there's additional structure or steps, or when
15 it provides important antecedent basis for a later limitation
16 that wouldn't be understood absent the preamble language.

17 When we go through the claims here, we don't see any
18 of these with respect to the majority of the preamble
19 limitations.

20 And I'd like to start first with the method preambles,
21 if we could go to Slide 17. And I move to Slide 18.

22 So the method preambles are very similar and both
23 discuss a method of cleansing a colon of a subject or a method
24 for cleansing the colon. Now, in prior cases involving method
25 patents, we see how the federal circuit has treated them.

1 They're not limiting when the steps are performed the same way
2 regardless of whether the preamble is a limitation; where the
3 preamble body was merely duplicative of limitations in the body
4 of the claim; when there was no clear reliance on the statement
5 of intended use during the prosecution; or where the claim
6 bodies recite all of the necessary steps.

7 If we could go to Slide 19.

8 Here, the two preambles are both "a method of
9 cleansing a colon of a subject" and "a method of cleansing the
10 colon," and that's for the '864 and '498 patents respectively,
11 Claim 1. But importantly, when you look at the rest of the
12 claim, it recites a complete method. It tells you every single
13 step you need to perform for the method: Administering a first
14 dose, administering a volume of water, administering a second
15 volume of water and a third, administering the second dose.

16 And then in Section H of Claim 1 of the '846 patent
17 and Claim 1 of the '498 patent, Section D, they result with
18 cleansing of the colon of the subject. That phrase, "cleansing
19 of the colon of the subject," is readily understood by a person
20 of skill in the art without any reference to the preamble and
21 it's redundant of the intended use of the method that's recited
22 in the preamble.

23 So you could delete from both of the method claims the
24 phrase "a method of cleansing a colon of a subject" or "a
25 method of cleansing the colon" from the preamble and still have

1 a complete invention for the purpose of cleansing the colon,
2 and the claim in the last two limitations would expressly tell
3 the person of skill in the art that.

4 If we could turn to Slide 20.

5 In the *Bristol-Myers* case, the federal circuit
6 explains that the "preamble for a method claim is not limiting
7 when the steps of the method are performed in the same way,
8 regardless of whether or not the patient experiences the
9 intended result in the preamble."

10 And then in the *American Medical Systems* case, the
11 federal circuit explained that a "preamble is not limiting when
12 the body of the claim contains all the steps necessary to
13 practice the invention." That's exactly the situation we have
14 here with respect to the asserted claims of the method
15 patents.

16 If we could go to Slide 21.

17 The method patents contain complete methods unto
18 themselves in the claim without any necessary step or added
19 structure from the preamble. The preambles don't affect in any
20 way how those steps are performed or the result of colon
21 cleansing that those steps achieve. The preambles simply add
22 nothing to the understanding of these claims.

23 Now, if we could turn to Slide 22, we see that exact
24 redundancy for each of the two representative method claims,
25 Claim 1 of the '498 patent and Claim 1 of the '864 patent. The

1 body recites "wherein the first and second doses cleanse the
2 colon of a subject." There's no need for an antecedent basis.
3 That phrase is perfectly understood by the skilled artisan.
4 Same for the '864 patent, the body says "wherein the colon
5 cleansing composition cleanses the colon."

6 Again, that language is readily understood by the
7 skilled artisan, there's no antecedent basis necessary for the
8 preambles. You could literally delete the limitations of the
9 preambles and not change the substance of the claims. And
10 under the *Summit* case, a preamble is not limiting where it is
11 "duplicative of the limitations in the body of the claim and
12 merely provides context for the limitations," which is exactly
13 the situation we have here.

14 If we could turn to Slide 23.

15 With respect to the method claims, there was no clear
16 reliance by the plaintiff during prosecution on these colon
17 cleansing preamble limitations. There was some discussion
18 about the distinguishing of the Bachwich reference. And if we
19 look at the prosecution history of the '498 patent, the
20 patentee argues that "Bachwich does not teach the specific
21 water regimen claimed in the method."

22 "Bachwich teaches ingestion of a clear liquid prior to
23 administering the formulation."

24 Those distinctions don't relate to the preamble or the
25 colon cleansing at all, they relate to the specific enumerated

1 limitations in the body of the claim. And so this was not the
2 basis for distinguishing the prior art and not a basis to
3 construe the preamble as a limitation.

4 If we turn to Slide 24, we see the same with respect
5 to the '864 patent. The examiner during prosecution in the
6 notice of allowance stated that: "An updated prior art search
7 did not disclose a reference that teaches a method of cleansing
8 the colon of a subject comprising the steps recited in the
9 instant claim." So the focus was not on the preamble, it was
10 on the recited steps of the instant claims. There were no
11 specific arguments made by the patentee with respect to the
12 preamble or the cleansing a colon limitation with respect to
13 the method claims.

14 Now, if we turn to Slide 25.

15 There was a discussion about antecedent basis in
16 counsel's argument. A preamble that provides "antecedent
17 basis" for a later claim term may be limiting, but the preamble
18 has to provide "context that's essential to understanding the
19 meaning" of the term or phrase later in the claim.

20 As we saw earlier, the phrases for cleansing the colon
21 that appear later in the claims are not aided in any way by the
22 preamble language. The preamble doesn't provide a further
23 understanding, it doesn't provide further structure or context.
24 It merely repeats the same language that was apparent in the
25 preamble.

1 And in the *American Medical* case, the preamble recited
2 "photoselective vaporization of tissue" and the claim body
3 later recited just "the tissue." Even that difference where
4 the preamble had slightly more information about what the
5 tissue was was determined not to be limiting because it didn't
6 add to the structure of the invention.

7 If we could turn to Slide 26.

8 Now, plaintiffs relied on the cases cited here, the
9 *Eli Lilly*, the *Sanofi*, and the *Jansen* cases. The *Eli Lilly*
10 case, the preamble recited a "method for treating a headache in
11 an individual," and in that case the preamble was determined to
12 be limiting because later the claim recited an "effective
13 amount." You couldn't understand the term "effective amount"
14 unless you knew what you were treating, which was treating
15 headache. So the preamble provided essential context for
16 understanding the body of the claim. That's not the case
17 here.

18 The same is true with the *Sanofi* and the *Jansen* cases,
19 and we have no similar tie between a limitation in the claim
20 that needs further clarification and the preamble language.

21 So with respect to the method claims, they're simply a
22 statement of intended use. They don't provide antecedent
23 basis, they don't provide essential structure, they don't add
24 anything to the claim that isn't already there in the last
25 provision of each claim, and therefore, under the controlling

1 federal circuit precedent, we don't believe that they are
2 limitations.

3 Now, I'd like to shift to the preamble terms in the
4 composition patents, and this one presents a more nuanced and
5 difficult issue than I think the method claims do.

6 So the composition preambles, if we could go to Slide
7 29, we've broken them into two pieces: The first being "a
8 solid oral formulation" and the second being the limitation
9 "for cleansing a colon of a subject."

10 Now, plaintiffs would like to treat this as one
11 continuous limitation, but for purposes of explaining it I'd
12 like to break them into two and explain why.

13 So the first part, the "solid oral formulation" does
14 recite some structural features. And the question is, are
15 those sufficient to constitute a claim limitation? And this is
16 probably the most difficult part of the analysis under the
17 federal circuit's case law.

18 And then the second question becomes, is the
19 limitation "for cleansing a colon of a subject" necessary
20 language for claimed compositions or do you have a complete
21 invention without that language?

22 So I'd like to start with the "solid oral formulation"
23 piece. And if we could go to Slide 30. The federal circuit
24 has told us that "not every preamble reference to additional
25 structure is limiting, even when the structure is noted in the

1 specification and even, indeed, when the structure is
2 'underscored as important by the specification.'"

3 And in the *Arctic Cat* case, the preamble recited a
4 "personal recreational vehicle," and the preamble was
5 determined not to be limiting because it didn't supply
6 structure that was needed to make a "structurally complete
7 invention."

8 The federal circuit's case law on this issue is, I'll
9 say, ambiguous at best as to when something adds enough
10 structure in the preamble to be limiting and when it doesn't.

11 THE COURT: But don't you think in this case it's -- I
12 mean, I think it's very different than a car, or whatever the
13 recreational vehicle is, particularly given the history of the
14 issues with patient compliance and the different forms of
15 liquid versus solid. It seems to me that in this particular
16 case, the beginning, what you're calling the first part, "a
17 solid oral formulation" actually does add something significant
18 and contextual here because if you understand the whole
19 purpose, which then is discussed elsewhere -- right? -- in the
20 specification is because of compliance issues and because if
21 you don't have compliance, then you don't have effectiveness.

22 So while it may not be 100 percent necessary for a
23 complete structure, I think it's very different from things
24 that can only really be in one physical structure.

25 MR. ZIMMERMAN: Right. And with respect to all of the

1 things we're talking about, the prior art and the claims, Your
2 Honor, they're all oral. There are none that are taken
3 otherwise. They're all formulations. The only real hard part
4 is that solid limitation.

5 THE COURT: Right.

6 MR. ZIMMERMAN: And I can see that being a limitation
7 and that's why I think that's the hardest piece of the whole
8 debate.

9 THE COURT: I think that's your -- the way I look at
10 it, I think that's your biggest problem, quite frankly. From
11 your perspective, from your client's perspective, I think -- if
12 it said just "an oral," I agree with you, you could take a
13 tablet, you could drink it, you could put it on your tongue and
14 it can dissolve, right? We've all done all those things. But
15 to say "a solid oral formulation" I think makes this language
16 different than some of the cases that you cite and rely on.

17 MR. ZIMMERMAN: And I agree that that's the very close
18 issue, and that's why I acknowledge that it was the most
19 difficult for us at the beginning. I think it's the one word
20 "solid," and that's why we parsed them that way.

21 And I can see the "solid" being read as a limitation
22 or not as a limitation. I think it's a close call under the
23 federal circuit's precedent as to when it is and when it isn't.

24 Now, if we go to Slide 32, which is the "cleansing the
25 colon" part. So preambles that describe the use of an

1 invention -- I am sorry, if we could go to the second piece,
2 the "cleansing the colon" part.

3 There's no dispute that that's a statement of the
4 intended use of the formulation. That piece doesn't impart any
5 structure on the claim composition, it doesn't provide any
6 antecedent basis for any of the terms, and that "cleansing the
7 colon" piece was not in any way argued as the limitation that
8 was overcome for prior art purposes to gain allowance of these
9 claims.

10 THE COURT: But do you think it's fair to separate the
11 preamble into two pieces like that? Is that the way I'm
12 supposed to look at it? Or do I have to look at it in total?

13 MR. ZIMMERMAN: I think it's fair, and I'm getting
14 ready to turn to why you're allowed to parse them that way.

15 THE COURT: Okay.

16 MR. ZIMMERMAN: And I think it's very fair when one is
17 a structural piece, like the solid oral formulation, and the
18 other one is a statement of intended use.

19 THE COURT: Okay.

20 MR. ZIMMERMAN: And the statement of intended use, we
21 see from the *Catalina Marketing* case, is "only limiting if the
22 patentee clearly and unmistakably relied on the intended use to
23 distinguish prior art." And I don't think that's the situation
24 we have here.

25 THE COURT: But in those cases was the court parsing

1 out or was the preamble only talking about intended use?

2 That's my question.

3 MR. ZIMMERMAN: I'm going to jump ahead then to Slide
4 37, if we can. And I will come back to where we were.

5 THE COURT: Okay.

6 MR. ZIMMERMAN: So even if we say the "solid oral
7 formulation" is a limitation, the intended use for "cleansing
8 the colon" is not limiting. The structure in one part of the
9 preamble doesn't make the entire preamble limiting under
10 federal circuit case law.

11 And in the *TomTom* case, the federal circuit explained
12 that the court erred in determining that it had to construe the
13 entire preamble if it construed a portion of it; that the
14 phrase in the preamble destination tracking system of at least
15 one mobile unit provides a necessary structure for Claim 1,
16 does not necessarily convert the entire preamble into a
17 limitation, particularly one that only states the intended use.

18 So the federal circuit has expressly condoned this
19 parsing of preambles where you have a structural component and
20 an intended use component.

21 Now, can I get --

22 THE COURT: Yes.

23 MR. ZIMMERMAN: I wanted to grab plaintiffs' slides.
24 If you go to Slide 26 of plaintiffs' presentation. And I
25 apologize that I can't put that one on the screen, Your Honor,

1 since it's not my presentation.

2 THE COURT: That's okay.

3 MR. ZIMMERMAN: They cited the *SIMO* case. And the
4 quote reads: "We decline to parse the preamble in the way
5 where, as here, the preamble supplies the only structure of the
6 claimed device and the disputed language does not merely
7 identify an intended use or functional property but is
8 'intertwined with the rest of the preamble,' and supplies
9 structure noted in the specification."

10 That's not the situation we have here. They are
11 readily distinguishable pieces. You have the "solid oral
12 formulation" piece, which is structural and relates to the
13 formulation that's later claimed with all of the pieces, and
14 then you have the "cleansing the colon" limitation that is
15 merely a statement of intended use and doesn't have any
16 structural properties to it.

17 You would have the exact same tablets or composition
18 if you took out the intended use "cleansing the colon" piece.
19 It doesn't add anything. And in fact, what it does is it
20 attempts to convert the composition claims into a method-type
21 component by giving you the intended use. So the parsing of
22 the two is, in fact, consistent with federal circuit precedent
23 and why we presented it that way.

24 Now, if we could go back to Slide 34.

25 There's no clear reliance during prosecution of the

1 composition patent on the colon cleansing. They talk about
2 electrolyte shifts and cleanse the colon generally, but no
3 specific distinction between the prior art. The distinction
4 that was drawn was based on the electrolyte shifts, not any
5 distinction in cleansing the colon.

6 And then if we go to Slide 35. Again, the examiner
7 said he did an undated prior art search and it doesn't teach
8 all of the recitations of the claim. There's no focus on any
9 one particular piece, let alone the "cleansing of the colon"
10 preamble language.

11 If we go to Slide 36.

12 There's no dispute that the patentee did not rely on
13 the preamble language to distinguish prior art during
14 prosecution of the '697 patent and no argument made as such, so
15 without that clear reliance, the "for cleansing a colon"
16 language is not a limitation of the composition claims.

17 Excuse me, Your Honor.

18 THE COURT: Take your time.

19 (Brief pause.)

20 MR. ZIMMERMAN: Now, if we get to construction of the
21 preambles, if we could go to Slide 38, the party -- sorry, go
22 to Slide 39.

23 The parties disagree on then what the meaning of these
24 terms would be. The preambles don't recite any particular
25 degree of colon cleansing, nor does the specification provide

1 any particular degree. Plaintiffs' language of the "adequate
2 visualization" reads in a requirement that you have to do colon
3 cleansing to a particular degree.

4 The specification doesn't give you any measure of
5 what's adequate, how do we assess adequacy, how do we compare
6 different compositions. They want to read in a particular
7 limit so that they can say prior art doesn't mean that limit.
8 That degree doesn't show up anywhere in these patents. And
9 that's why Lupin has proposed that the "colon cleansing" means
10 some degree of colon cleansing. This is consistent with the
11 prior art where you have kind of varying degrees that are going
12 to change by individual compliance with the dose, what you
13 actually use. And there's nothing in the intrinsic evidence
14 that requires a particular degree of colon cleansing.

15 If we go to Slide 40.

16 Lupin's proposed construction is that you have some
17 degree of colon cleansing. Now, plaintiffs say that Lupin's
18 proposed construction contradicts the specification's
19 description of "colon cleansing as sufficient to permit
20 adequate visualization of the intestine mucosa." There's no
21 support for this adequate visualization requirement, and we
22 would be in a position where it injects more ambiguity into the
23 claim than we start with.

24 THE COURT: So how is that different from saying "some
25 degree"? Aren't they both making it ambiguous? They're just

1 different words.

2 MR. ZIMMERMAN: "Some degree" says we're not going to
3 put a number on it as long as there is colon cleansing to some
4 amount. We don't have to quantify it because the specification
5 doesn't quantify it, the claims don't quantify it.

6 "Adequate visualization," in contrast, as plaintiffs
7 propose, put a limit on it. They're saying there's going to be
8 some degree that's not enough to meet this "adequate
9 visualization" requirement, and so some things qualify and some
10 don't. And I think the argument that we're going to hear later
11 is the prior art doesn't get you sufficient visualization, it
12 doesn't meet this requirement, that doesn't appear anywhere in
13 the claim that's been read in under the guise of "colon
14 cleansing."

15 And if we could go to Slide 41.

16 So in the event the Court determines that the "solid
17 oral formulation" language is limiting, we would be in a
18 position where Lupin's construction would be "a formulation
19 provided as a solid that may be administered by the oral
20 route." I don't think there's any dispute between plaintiffs
21 and defendants with respect to what that would then be. But we
22 would still contend that the "for cleansing the colon" is not a
23 limitation.

24 Did you have any questions, Your Honor?

25 THE COURT: Give me one second.

1 (Brief pause.)

2 THE COURT: Not right now. Thank you, counsel.

3 MR. ZIMMERMAN: Thank you. I will turn it over to
4 opposing counsel.

5 THE COURT: Can you give me one second, counsel. Just
6 let me look at my notes and make sure I don't have any
7 questions.

8 (Brief pause.)

9 THE COURT: Okay.

10 MS. PIROZZOLO: Your Honor, may I respond just briefly
11 on a couple of points?

12 THE COURT: Yes.

13 MS. PIROZZOLO: Your Honor, first of all, just as a
14 point of clarification with regard to the defendants' proposed
15 construction of colon cleansing, I just want to be clear that
16 we did not propose a construction that states adequate
17 visualization. We're proposing that colon cleansing be given
18 its plain and ordinary meaning.

19 THE COURT: It is what it is, whether it's one
20 percent, ten percent or whatever other -- are you aware of any
21 other patent that has described it any way different with a
22 sufficient amount or adequate visualization or by percentage?

23 MS. PIROZZOLO: As I stand here, I'm not, but these
24 claims don't have any percentage in them.

25 THE COURT: Right. And I'm assuming if your client

1 felt that it could guarantee a hundred percent or absolutely,
2 then you would want to patent that and put that in there,
3 right?

4 MS. PIROZZOLO: That could be, but I think Your Honor
5 has talked about the difficulties with that.

6 THE COURT: Okay.

7 MS. PIROZZOLO: So that's the first point. We really
8 have just proposed plain meaning of that term.

9 THE COURT: You want me to leave it as it is and use
10 its plain and ordinary meaning, which would mean to whatever
11 degree that it is effective, which is highly dependent upon how
12 the patient uses it.

13 MS. PIROZZOLO: And this is something a person of
14 ordinary skill in the art would understand, what colon
15 cleansing is.

16 THE COURT: Because they understand that no matter
17 what the medication is or whatever is administered is wholly
18 dependent upon how it is taken by the patient and all these
19 other external factors, right, a POSA would know that?

20 MS. PIROZZOLO: And here the point of the claims is a
21 formulation for use for that purpose, and a person of ordinary
22 skill in the art would understand that the purpose of the
23 formulation is for colon cleansing and not for something else,
24 a different application.

25 And just briefly, Your Honor, the phrase "solid oral

1 formulation for cleansing a colon" should not be parsed. It
2 should be treated like the limitation, as the examiner noted in
3 the reasons for allowance.

4 Just briefly, these preamble cases are challenging,
5 but the *TomTom* case, in the *TomTom* case the court explicitly
6 found that the portion of the preamble that was read out of the
7 claim was not important for the invention.

8 Here we have -- you know, and these cases are all very
9 fact specific and governed by the intrinsic evidence in the
10 case. Here we have a very different situation where the entire
11 focus of the intrinsic evidence in the specification is on
12 colon cleansing.

13 THE COURT: Can you tell me what slide that is that
14 you had, the response from the claims examiner? Just because I
15 want to look at it again.

16 MS. PIROZZOLO: Let me get that. Do you mean the
17 examiner's notice of allowance?

18 THE COURT: Yes.

19 MS. PIROZZOLO: I believe that is Slide 27.

20 THE COURT: Is that 24 or 27?

21 MS. PIROZZOLO: 24. I am sorry, Your Honor.

22 THE COURT: Okay. Just give me one second to read it
23 again.

24 (Brief pause.)

25 THE COURT: Okay.

1 MS. PIROZZOLO: Unless Your Honor has any further
2 questions --

3 THE COURT: I don't. Thank you.

4 MS. PIROZZOLO: Thank you, Your Honor.

5 Mr. Noyes will talk about "consisting essentially of."

6 MR. NOYES: May I proceed, Your Honor?

7 THE COURT: Yes.

8 MR. NOYES: Thank you. Chris Noyes for Braintree and
9 Sebela. And as Ms. Pirozzolo stated, I'll be addressing the
10 "consisting essentially of" terms, and those terms appear in
11 the '864 and the '498 patents, Claim 1 of those patents. So
12 those terms actually only implicate 7 out of the remaining 19
13 patents at issue on the case, they are not in 12 of the patents
14 that have been stipulated to in this case.

15 THE COURT: Counsel, can we just do one thing? I
16 don't want to take a break between the two of you, so why don't
17 we just take a quick ten-minute break now and then we'll switch
18 to the "consisting essentially of" and we can all kind of
19 regroup. So just give me ten minutes and I'll be right back.

20 THE COURTROOM DEPUTY: All rise.

21 (Brief recess taken from 11:38 a.m. to 11:56 a.m.)

22 THE COURTROOM DEPUTY: All rise.

23 THE COURT: Okay. Please be seated. I like to reset
24 before we switch gears, so it's helpful to me. All right. I'm
25 ready.

1 MR. NOYES: Thank you, Your Honor. And again, Chris
2 Noyes for Braintree.

3 And as Ms. Pirozzolo mentioned earlier, the claim term
4 "consisting essentially of," that is a term that has an
5 established legal meaning, the federal circuit has determined
6 what it means. And in this case there's actually no dispute
7 about what that term means, "consisting essentially of."

8 And Mr. Zimmerman and I just actually conferred, we
9 agree "consisting essentially of" has an established meaning,
10 we agree with that meaning. I'll come to that in a moment.

11 And if you read the briefs, Your Honor, you'll see the
12 dispute has evolved over time. And the dispute has become
13 this: We say, Braintree says all the Court needs to do is
14 apply the established legal meaning of "consisting essentially
15 of" and nothing more. We're proposing a plain meaning
16 construction.

17 Lupin's asking you to do more. They're asking you to
18 go further and answer this first question, what are the basic
19 and novel properties of the claimed composition at claim
20 construction?

21 We proposed the basic and novel properties, we've
22 identified those to Lupin and what they are, and I'll come to
23 that in a moment. Those are clearly supported by the claims,
24 the specification and the prosecution history. But, Your
25 Honor, it's our position you don't need to reach that

1 determination now. You can based on the intrinsic evidence,
2 but you don't need to do so because there's nothing that really
3 turns on the definition of basic and novel properties, at
4 least --

5 THE COURT: Well, that was going to be my question.
6 Like, what does it matter? Right? Why am I dealing with this
7 now?

8 MR. NOYES: Yes.

9 THE COURT: Does it matter? Because sometimes I miss
10 it, I don't get it, I don't understand it.

11 Is there some reason that it matters now?

12 MR. NOYES: Our position, Your Honor, to be very
13 clear, is you don't need to decide this now.

14 THE COURT: That it would be a summary judgement
15 issue?

16 MR. NOYES: Well, it would be a trial issue, Your
17 Honor. Because what the basic and novel properties of the
18 invention are, really from the perspective of a person of
19 ordinary skill in the art -- this is an ANDA case. There's no
20 jury, there's no jury to instruct. You're going to hear the
21 evidence, you're going to hear the experts, you're going to
22 hear the inventors. You'll have an opportunity to have the
23 full and complete record.

24 And moreover, Your Honor, that will be after the
25 parties have gone through expert discovery. We have not yet

1 exchanged expert reports on invalidity, which is the only issue
2 remaining in the case. That will clarify whether there
3 actually is a dispute about this.

4 THE COURT: Well, I'm assuming it's not going to
5 happen, but what if all the experts agree that three of these
6 things are and there's only one, so why would I decide four
7 things?

8 MR. NOYES: Exactly, Your Honor. It's just premature
9 at this time. Our position is it's premature, there's no need
10 for you to go this far and identify the basic and novel
11 properties when we're still litigating the case. And the
12 issues, I think, will be clarified during expert discovery.

13 I think to start it off, Your Honor -- and Mr.
14 Zimmerman can correct me if I'm wrong -- as a non-infringement
15 position -- of course there's now been a stipulation on
16 infringement. It may be an invalidity issue, and in their
17 reply brief they reference indefiniteness, but the parties have
18 agreed to defer the consideration of indefiniteness until after
19 expert discovery.

20 THE COURT: Well, that's why I was a little confused,
21 because even if that is an issue, it's still not an issue for
22 me today, right?

23 MR. NOYES: I agree with you, Your Honor. I don't
24 think you need to reach that issue today because the parties
25 will exchange expert reports on whether the claims are definite

1 or not to the extent that is an issue in this case.

2 THE COURT: So in light of the parties' stipulation
3 now, which didn't exist obviously when the briefings were filed
4 -- right? -- which I think for the record is ECF 82, what do I
5 have to decide with respect to this issue?

6 MR. NOYES: Our position, Your Honor, is all you need
7 to decide is that plain meaning applies, which is undisputed,
8 what "consisting essentially of" means. And I'll just go there
9 very quickly, Your Honor.

10 THE COURT: Okay.

11 MR. NOYES: Well, let me just be very clear. We have
12 proposed essentially a plain meaning construction for both
13 Claim 1 and -- Claim 1 of '864 of the '498 patent. All we have
14 added is what the federal circuit has said "consisting
15 essentially of" means, which is, can additionally include other
16 components that do not materially affect the basic and novel
17 properties of a composition.

18 THE COURT: But then I don't need to decide then what
19 are those things right now.

20 MR. NOYES: Correct, that is our position, you don't
21 need to at this time. You could, but we don't think you need
22 to.

23 Lupin, Your Honor, has proposed a slightly different
24 construction. They've added this concept of colon cleansing
25 properties to the proposed construction, which they've said in

1 their briefing now is their attempt to define the basic and
2 novel properties of the invention.

3 We've proposed an alternative to that in our
4 interrogatory responses, which I can get into, Your Honor, if
5 you'd like. I can also sit down and hear from Mr. Zimmerman.
6 But our position is we have a position on basic and novel
7 properties, it's supported by the specification. I'm happy to
8 walk through that now and why that position is supported and
9 why their position is wrong, but, Your Honor, we don't believe
10 it's necessary given where we are in the case with the
11 infringement stipulation with indefiniteness to the extent
12 that's even an issue being deferred.

13 THE COURT: Can I hear from the defendant first on
14 that issue as to why I should even go there because --

15 MR. NOYES: Yes.

16 THE COURT: Obviously, we always like to decide less
17 than necessary. But if I have to decide, I will decide it.
18 But I will tell you, in reading this -- and I do read all the
19 briefs. I was up until 11:00 rereading them again. When I
20 went back and looked at the stipulation -- and yes, the
21 briefing has changed a little bit -- I was a little, I won't
22 say confused, but trying to figure out what each of your
23 positions now was as to how much, if any, of this issue do I
24 have to decide.

25 So can I hear from defendants' position? Because what

1 I'm hearing you say is I don't need to do anything other than
2 say "consisting essentially of" is what the circuit has said it
3 is and it's its plain meaning and that's all we have to do for
4 now, and we'll go have our experts talk about whether this
5 versus that is or isn't part of that.

6 MR. NOYES: That's exactly right, Your Honor, that's
7 our position.

8 THE COURT: Okay. So let me hear from defendant,
9 whoever is going to address that. Can you help me out as to
10 why I need to address this now; what, if any, impact it has;
11 and is it really prudent to address it now on the record the
12 way that it is given that we have no expert?

13 So for example, you know, there are times where I have
14 preliminary injunction hearings, I had one last year, where I
15 had all these experts testify and I had to decide in a
16 preliminary injunction context whether or not it was more
17 likely than not -- you know, in the terms of a composition
18 patent, whether or not it was more likely than not. That's not
19 where we're at, right? We have nothing here.

20 MR. ZIMMERMAN: We have no expert testimony at this
21 point, Your Honor, but we do have an agreement among counsel
22 that the meaning of "consisting essentially of" is that it
23 excludes items except for those that do not materially impact
24 the basic and novel properties of the invention. So we're
25 going to have a dispute between the parties as to what's

1 included and what's excluded from this claim. That dispute is
2 coming. Whether it comes now or whether it comes at the end of
3 expert discovery, the parties have clear differences as to what
4 the basic and novel properties are.

5 THE COURT: And that's what my question is, how do I
6 decide that now without any expert testimony when it's clearly
7 at the heart of an issue that you dispute? It's great that you
8 agree that this is the confines of the legal issue, right, but
9 should I or how could I -- being a lawyer, not a scientist or a
10 chemist -- how can I make that decision based solely on your
11 arguments?

12 Because you don't agree on that issue, right?

13 MR. ZIMMERMAN: And if we could go to Slide 4, Brian.

14 THE COURT: And I just want to talk about just this
15 issue.

16 MR. ZIMMERMAN: Just this issue, Your Honor.

17 THE COURT: Is it in your slides you already gave me
18 or something different?

19 MR. ZIMMERMAN: It is. Slide 7.

20 THE COURT: 7?

21 MR. ZIMMERMAN: Yes. The federal circuit told us in
22 the *HZNP* case, "Courts evaluating claims that use the phrase
23 'consisting essentially of' may ascertain the basic and novel
24 properties of the invention at the claim construction stage,
25 and then consider if the intrinsic evidence establishes what

1 constitutes a material alteration of those properties."

2 So --

3 THE COURT: But what --

4 MR. ZIMMERMAN: -- it's a "may."

5 THE COURT: That's my question.

6 MR. ZIMMERMAN: It's within your discretion. You have
7 the intrinsic evidence, you can hear the parties' dispute about
8 what those are and make a decision on the intrinsic evidence.
9 And I will tell you from a selfish standpoint, it does help the
10 experts then write their reports if we know what's in and
11 what's out.

12 THE COURT: Okay.

13 MR. ZIMMERMAN: Alternatively, you could say claim
14 construction, I'm just going to say things that don't affect
15 the basic and novel properties, and we'll deal with it after
16 the experts fully brief it and it will be a disputed issue for
17 trial.

18 THE COURT: I don't even have to say that. I just
19 have to say, as you have all both agreed -- right? -- that
20 that's what it is.

21 MR. ZIMMERMAN: Yes.

22 THE COURT: So I guess I will hear from you, but I
23 will tell you that my inclination is, after reviewing
24 everything and given how things have changed or evolved in
25 this case -- and look, I will say again, I always appreciate

1 and greatly appreciate when you continue to narrow the issues.
2 I think it makes it better for everyone. It's money better
3 spent for your clients that we focus on the most important
4 issues. It makes it easier for me to address them in a timely
5 manner.

6 I will hear from you as to what your position is, but
7 my -- I tend to agree now that it's an issue that would be
8 better decided by me on a fuller record. But I will hear from
9 both of you.

10 So let's switch back and I will hear from plaintiff as
11 to what their position is, but that is my initial inclination.

12 MR. ZIMMERMAN: Thank you, Your Honor.

13 THE COURT: I'm not saying you can't change my mind
14 but...

15 MR. ZIMMERMAN: Understood, Your Honor.

16 MR. NOYES: So, Your Honor, just to level set again
17 here, again, "consisting essentially of," the term itself is
18 not in dispute for purposes of this claim construction hearing,
19 is in the '498 patent Claim 1 and the '846 patent Claim 1.

20 And as I said, for all of the asserted claims of the
21 '498 patent and the '846 patent, this term would apply, but
22 it's not at issue in the 12 remaining claims. So another
23 reason why at the end of the day I'm not committing to dropping
24 these patents, but by the time we get to trial the claims will
25 be further narrowed so there's a possibility that this issue

1 goes away.

2 THE COURT: So there may be a possibility this issue
3 is not an issue at all.

4 MR. NOYES: Possibility, Your Honor. Again, I'm not
5 committed to dropping these things, but it is a possibility.

6 THE COURT: I understand.

7 MR. NOYES: As we have all agreed, the federal circuit
8 has agreed that by using the term "consisting essentially of,"
9 the drafter signals that the invention necessarily includes the
10 listed ingredients -- so in your case, the sulfate, the sulfate
11 salts, and the potassium chloride -- but it's also open to
12 unlisted ingredients that do not materially affect the basic
13 and novel properties of the invention.

14 And a lot of these cases that were briefed to you,
15 Your Honor, the dispute is all about that last part, what
16 are the ingredients that are unlisted that could be included
17 but would affect the basic, novel properties. Not so much what
18 the basic and novel properties are, it's more can you include
19 X, Y, Z component and would that affect the claimed invention?

20 Now, again, Lupin agrees with us on the meaning of
21 "consisting essentially of" in the law and we've talked about
22 the different constructions, but I want to talk about why it's
23 appropriate, Your Honor, to defer, and you're on solid legal
24 ground by deferring. Many courts have done the same thing in
25 this district, in the District of Delaware. And here's just a

1 sampling of some of them where -- there's the *Senju* case out of
2 this district, the *Lonza* case out of this district, the *Church*
3 & *Dwight* case out of this district.

4 And notably, in the *Lonza* case and the *Church & Dwight*
5 case, in the *Azurity Pharma* case from Delaware, which is after
6 the federal circuit case *HPZM* that Mr. Zimmerman showed you,
7 there was no expert opinion. So it was the same procedural
8 posture in the sense that the court didn't have the benefit of
9 expert testimony.

10 And as Your Honor asked us, I recall at the science
11 day, the parties agreed not to present expert testimony at
12 claim construction, we agreed that we were not going to do that
13 in this context. So again, you will have the benefit of
14 experts at some point in this case, but you don't have the
15 benefit of expert testimony now.

16 This is the *HZNP* case that Mr. Zimmerman referred to.
17 And again, Mr. Zimmerman was clear, you're not required to
18 determine the basic and novel properties at claim construction.
19 You may, but you're not required to do so. But notably, that
20 case was all about indefiniteness, Your Honor. And what the
21 federal circuit was looking at was trying to figure out can the
22 basic and novel properties, do those need to be definite, do
23 those need to meet that requirement of the patent law? And the
24 court there said, yes, they need to satisfy the definiteness
25 requirements, and you apply the legal standard under the

1 Supreme Court *Novartis* case to determine whether or not the
2 basic and novel properties are definite.

3 Again, we don't have that dispute right now. There's
4 a suggestion I think in the briefing that we might have that
5 fight, but we haven't had that fight yet. It hasn't been
6 briefed, we haven't had the opportunity to have experts address
7 it. We could have that fight and then we'll bring it to Your
8 Honor once we do have that fight.

9 Another thing, Your Honor, there are times when
10 there's a dispute about the basic and novel properties at claim
11 construction and this is an example from Delaware. This was a
12 letter the parties submitted to Judge Andrews where they're
13 debating what the basic and novel properties are, what can be
14 included, what can be excluded in a claim with "consisting
15 essentially of," and the court there decided to adopt the plain
16 meaning construction that Braintree is proposing in this case.

17 Now, getting to the second point, Your Honor, if you
18 were to decide that this was an appropriate time to determine
19 the basic and novel properties of the claimed inventions, what
20 are they? And we have proposed to Lupin, in a response to an
21 interrogatory that propounded right before opening claim
22 construction briefs went in, that the basic and novel
23 properties are the specific balanced combination, sodium
24 sulfate, magnesium sulfate, and potassium chloride in the
25 claimed amounts, so in the specific amounts claimed, which

1 resulted in a phosphate-free composition that is both effective
2 and safe for colon cleansing; i.e., does not cause dangerous
3 fluid or electrolyte shifts in a patient.

4 And, Your Honor, our position is you don't need to
5 decide this, but if you determined that you were to do so, it
6 is supported by the intrinsic evidence. And if we start with
7 the claim language, of course the claims are clear. It's
8 specific ingredients, sodium sulfate, magnesium sulfate, and
9 potassium chloride, in specific amounts; and that those
10 specific ingredients and the specific amounts are used to
11 cleanse the colon of a subject.

12 And, Your Honor, just so I'm clear, I'm only focusing
13 on the '864 patent here, not the '498, because really there's
14 no difference in terms of the argument with respect to
15 "consisting essentially of."

16 Now, the specification also supports Braintree's
17 proposal. Again, you'll see the specification is replete with
18 references to the specific amounts of the specific ingredients
19 and the claimed colon cleansing compositions. The
20 specification also discloses that the inventors surprisingly
21 found that you could only use two sulfate salts, as opposed to
22 the three in the prior art SUPREP, which we talked about at
23 science day, which was that smaller 16-ounce-volume
24 composition.

25 The specification also goes on to emphasize that it's

1 not only just the combination of salts, it's the balance of the
2 salts. And that's really the magic of this invention, you'll
3 hear that throughout the trial when the inventors testify,
4 which is finding the correct balance of the osmotic agents, the
5 sulfate salts, and the electrolytes so you could have an
6 effective colon cleanse but it's safe. Doesn't cause
7 clinically significant electrolyte shifts, doesn't have all the
8 phosphate in it that caused all the renal problems, the
9 kidney problems. So that's the magic of this invention and
10 that's what the specification discloses over and over
11 again.

12 And again, specification is clear that the phosphate
13 salt tablet formulations, the OsmoPrep and others, VISCOL,
14 which was another phosphate-based preparation, those had salts
15 and phosphate and they became associated with risk of renal
16 failure due to calcium phosphate deposition. So the
17 specification is certainly describing safety risks associated
18 with the prior art phosphate preparations.

19 And, Your Honor, there's some suggestion in Lupin's
20 briefing -- again, this goes to the indefiniteness point, so it
21 hasn't been fully briefed at this point -- that "safe" might be
22 unclear or indefinite, and their proposal is simply colon
23 cleansing, but the specification is very clear that the
24 disclosed compositions are effective and safe to cleanse the
25 colon.

1 It goes on to say, "the formulations are effective to
2 induce purgation," "and are further safe and effective to
3 cleanse the colon." And then it also goes on to say, "the
4 disclosed compositions also do not cause clinically significant
5 electrolyte shifts."

6 So it's these dual problems of coming up with a
7 tablet-based preparation, a small-volume preparation that
8 didn't use phosphate because it was dangerous, could kill
9 people, and also could avoid clinically significant electrolyte
10 shifts.

11 And I'll just -- there are other discussions, Your
12 Honor, of avoiding clinically significant electrolyte shifts,
13 measuring electrolyte balances in the specification, consistent
14 with our proposal of the basic and novel properties.

15 And just briefly, Your Honor, now, Lupin has proposed
16 colon cleansing properties and they've said that they disagree
17 with our position. Interesting, though, in their briefing
18 they're citing the portions of the specification that also --
19 that we believe support our position. They cite to the fact
20 that it's these three specific components, the two sulfate
21 salts, the potassium chloride, that it's this combination of
22 salts that allows for inducing osmotic diarrhea for cleansing
23 the colon.

24 And notably, Your Honor, here they quote a portion of
25 what I just showed you, "the art has disclosed the use of

1 non-aqueous formulations of sulfate and phosphate salts.
2 However, these formulations have had drawbacks including
3 insufficient cleansing." Which, Your Honor, that quote
4 actually doesn't end at "cleansing."

5 If you go back to slide 56, that's the full quote
6 there where it says, "these formulations have had drawbacks
7 including insufficient cleansing and potential safety issues."
8 So again, it's not just cleansing, it's safety and effective
9 colon cleansing, that's part of the basic and novel properties
10 of these claimed compositions.

11 Your Honor, the prosecution history, you've seen some
12 of this before with the preamble arguments. This also supports
13 our proposal on basic and novel properties. Here, Mr. Chavous,
14 who was representing Braintree during prosecution, he was
15 discussing the background of colon cleansing products and
16 explaining to the examiner why magnesium citrate, disclosed by
17 this prior art reference Bachwich, could not simply be switched
18 for the magnesium sulfate recited in the claims. And then the
19 examiner suggested adding "consisting essentially of" since
20 magnesium citrate and Bachwich requires the co-administration
21 of osmotic agents such as PEG.

22 So what's going on here, Your Honor, is they're adding
23 "consisting essentially of" in response to arguments about the
24 prior art in the ingredients that are in the prior art, not
25 just colon cleansing properties but the osmotic agents, the

1 ingredients that are in the prior art.

2 And again, during prosecution Braintree is
3 distinguishing prior art based on the ingredients. Here, for
4 example, the prior art did not teach the use of sodium sulfate
5 as an osmotic agent.

6 During prosecution, Braintree is distinguishing the
7 prior art based on the fact that if you replaced -- if you
8 added -- if you replaced the prior art ingredients, here
9 magnesium citrate and PEG with magnesium sulfate, the skilled
10 artisan would be required to then go balance the electrolytes
11 and reformulate.

12 And again, this is the key, the magic of the invention
13 is this balanced formulation of salts and electrolytes that are
14 safe and effective, and that's what Braintree was
15 distinguishing during the file history in the '498 patent.

16 And finally, Your Honor, again, Braintree's
17 consistently distinguishing between prior art that's disclosing
18 the use of phosphate-containing formulations and the claimed
19 inventions and distinguishing the prior art based on the fact
20 that those formulations did not teach the avoidance of
21 clinically significant electrolyte shifts.

22 So, Your Honor, again, I'll end on where I started,
23 which is we're proposing plain meaning, there's no reason to go
24 beyond plain meaning. Lupin's construction, inserting this
25 concept of colon cleansing properties, it's just wrong based on

1 the intrinsic evidence.

2 But there's no reason to even get there at this point
3 because we've agreed about what "consisting essentially of"
4 means and we can have the fight with our experts. Your Honor
5 will have the benefit of hearing all the testimony and deciding
6 on a complete record -- to the extent there's a dispute about
7 this by the time we get to Your Honor for trial, you can have
8 the benefit of hearing the complete record.

9 THE COURT: I mean, even though it's an ANDA case,
10 ultimately -- and I'll be the fact finder and not a jury -- the
11 cases from the circuit that clearly talk about usually the fact
12 finder makes that, and that infers whether it's me or a jury in
13 a non-ANDA case, that discovery would have taken place by the
14 time we're at a fact finder, there would have been experts and
15 a full record.

16 And so I think that regardless of whether or not it's
17 an ANDA case or not, the fact that I'm functioning as a fact
18 finder there and I'm making legal determinations here in a
19 construction context are two totally different. So I tend to
20 agree with you, but I will hear from you, counsel.

21 MR. NOYES: Okay. Thank you, Your Honor.

22 THE COURT: Thank you.

23 MR. ZIMMERMAN: If we could start at Slide 7. May I
24 begin, Your Honor?

25 THE COURT: Yes. Give me one second.

1 (Brief pause.)

2 THE COURT: Yes.

3 MR. ZIMMERMAN: I'd like to return that it's within
4 the Court's power, as the federal circuit has announced, to, as
5 part of claim construction, determine the basic and novel
6 properties of the invention.

7 Now, we agree that "consisting essentially of" allows
8 for things that don't materially impact the basic and novel
9 properties, but at this point we have a dispute as to what they
10 are. And that's a claim construction dispute that is a legal
11 issue for the Court that you can decide at this stage,
12 otherwise, it will be a legal issue for the court at a later
13 stage after expert testimony.

14 THE COURT: I guess that's why I'm confused because
15 the cases I just looked at and that the plaintiff quotes say
16 it's for the fact finder. So you're saying -- I mean, whether
17 I'm the fact finder or a jury is a fact finder, fact finder to
18 me implies there's discovery, there's expert reports, you guys
19 have fleshed this issue out better.

20 What says it's a legal question?

21 MR. ZIMMERMAN: When the federal circuit says you
22 can do it as part of claim construction. The federal circuit
23 has made it clear that construing the scope and the meaning of
24 the claims is a legal determination for the court.

25 THE COURT: Was there testimony in those cases by

1 experts or expert reports or expert declarations?

2 MR. ZIMMERMAN: Even if there is expert testimony,
3 it's a legal issue. Now, it becomes a factual issue only to
4 the extent there is a disputed expert piece to it.

5 THE COURT: Well, I'm assuming we're going to have a
6 disputed expert piece, otherwise, we wouldn't be talking about
7 this issue, right?

8 MR. ZIMMERMAN: That's my assumption.

9 THE COURT: So that's my question. The cases that you
10 relied on where the court decided the case, was there experts
11 who supported dueling, for lack of a better word, declarations
12 or testimony when the court made the decision?

13 MR. ZIMMERMAN: I could tell you that there were --
14 that there was at least one expert deposition in the *Horizon*
15 case. The other cases -- if we could turn to plaintiffs' cases
16 just so we're on level set ground as -- they cited you a series
17 of them and said, oh, these are where the court said basic and
18 novel properties, that's the rule. And I believe it was Slide
19 48 of their presentation. And so we put the cases up here --
20 yes, I believe it's 48. It is.

21 And they said that all of those were construed to
22 mean "do not materially affect the basic and novel properties"
23 and nothing more, suggesting that the court did that. If you
24 look at the cases, *Church*, *Senju*, *Lonza*, *Azurity*, there was no
25 dispute between the parties. They agreed that that was the

1 construction. And if you look at the *Amgen* case, neither party
2 asked the court to define the basic and novel properties during
3 the claim construction phase.

4 So they're all cases where there was no dispute about
5 the basic and novel properties raised at the claims
6 construction stage. When they're raised, you end up in the
7 *Horizon* situation where the federal circuit has said you can go
8 ahead and decide those as a legal issue based on the intrinsic
9 evidence in the specification.

10 THE COURT: So convince me why I should do that here
11 before any discovery, before any expert reports.

12 MR. ZIMMERMAN: Okay. So when you look at the
13 patent --

14 THE COURT: But it doesn't say I have to, correct?

15 MR. ZIMMERMAN: It doesn't say you have to. I want to
16 be very clear, Your Honor. It's within your discretion to
17 decide it now or decide it after the expert testimony phase.

18 It does complicate the expert reports in that we
19 don't fully know what everyone's position is going to be and so
20 the experts are going to be making indefiniteness arguments on
21 what we think they're going to say the basic and novel
22 properties are and what the implications of those are. And
23 so it does lead to a cascade of expert report issues that
24 would not take place if we knew what the scope of this claim
25 was.

1 Now, in defining the basic and novel properties, we
2 look to the specification. If we could go to Slide 9. Lupin's
3 is very straightforward. The basic and novel properties relate
4 to colon cleansing. That's what this patent is about, that's
5 what the plaintiffs have said this patent is about.

6 Now, plaintiffs spent a lot of time talking about it's
7 the balanced combination of the three salts. The salts are
8 already claimed. They're expressly recited in the claims --

9 THE COURT: The amounts you mean?

10 MR. ZIMMERMAN: Yeah, what the three salts are and the
11 amounts. So that balance of salts can't be the basic and novel
12 properties of the invention because they're already recited.
13 It's what are the properties that come from this composition
14 that can't be materially affected by other things. And so the
15 composition leads to colon cleansing.

16 Now, plaintiffs want to say it's a phosphate-free
17 composition. Well, that's reading in a limitation that isn't
18 there. And then you have safe and effective.

19 Effective, as best we can tell, is a synonym for colon
20 cleansing. So the "effective" piece agrees with Lupin's
21 construction. And then the "safe" injects all kinds of
22 ambiguity to it because it's safe enough to the prior art
23 products, safe enough to give to people. And then there's
24 the second component of electrolyte levels and properly
25 balanced electrolyte shifts. There were other claims

1 that said clinically significant electrolyte shifts. That's
2 the indefiniteness argument that's been deferred by the
3 parties.

4 So if we're now injecting that in as one of the basic
5 and novel properties, then the same indefiniteness argument
6 may apply, but we don't know if the experts need to make that
7 because this is or isn't one of the properties that's going to
8 be included as the basic and novel properties. And so
9 resolving that now would allow the experts to fully address
10 whether that's part of these claims or not.

11 So from the specification, which of these is
12 supported? There's no doubt that Lupin's definition of
13 "effective colon cleansing" is the basic and novel property of
14 the invention or at least one.

15 If we go to Slide 9. The patent is replete with
16 references to colon cleansing. "These formulations" -- the
17 prior art -- "have had drawbacks including insufficient
18 cleansing," and the compositions at issue are "for cleansing a
19 colon," and those compositions "will induce purgation of the
20 colon" and "will lead to colon cleansing."

21 I don't think there's any dispute that colon cleansing
22 is at least the major novel property and the basic and novel
23 property of the invention. And if we had any doubt about that,
24 if we could go to Slide 12 -- I am sorry, slide -- go back to
25 Slide 11.

1 THE COURT: But if you read the rest of that part that
2 you don't have highlighted, it also says -- well, that you
3 didn't read -- "have had drawbacks including insufficient
4 cleansing," which to me is the same thing as effective; and
5 "potential safety issues," which to me is the same thing as not
6 dangerous. Right? Which is consistent with what they're
7 saying.

8 MR. ZIMMERMAN: If we go back to Slide 10.

9 THE COURT: I'm looking at Slide 10.

10 MR. ZIMMERMAN: Where are you, Your Honor?

11 THE COURT: I agree with you that "cleansing" is used
12 and that that's -- but they're also terms that are consistent
13 with what the plaintiffs are saying.

14 You say there's nothing that talks about they're
15 trying to limit by saying "phosphate free," "effective and
16 safe," but it is discussed here.

17 MR. ZIMMERMAN: There's no doubt they're all
18 discussed, but are those the basic and novel properties of this
19 invention or is this a colon cleansing invention? It has any
20 number of things that could be different --

21 THE COURT: And here is why I think I need expert
22 testimony, because I'll tell you a case I just had before. I
23 said to an expert who was sitting here, what's so novel about
24 this? There had never, ever, ever been a product -- and I'm
25 going to talk generally because obviously it was a sealed

1 proceeding.

2 There had never, ever been a product that used this
3 combination of things in this way to avoid this deadly event.
4 Right? And I'm really paraphrasing very generally. And when
5 the other expert came up, I said, can you tell me, had this
6 ever been done before? Nope.

7 I don't have that here. I have lawyers telling me
8 that this is what I should think it means, but I don't have
9 that here. So can you point to anything that would give me the
10 facts or the ability that I would be able to say what you're
11 saying is the way I should do it, other than argument, is the
12 way I should do it?

13 MR. ZIMMERMAN: Your Honor, we have the intrinsic
14 record of the patents and they contain references to multiple
15 different pieces in terms of colon cleansing, characterizing
16 the prior art as sulfate free, talking about electrolyte
17 shifts.

18 And if you need -- you know, I can't give you the
19 expert testimony. If you need the interpretation of those
20 written documents from what is basic and novel, then it would
21 have to be deference to an expert. You're right. I'm not
22 going to tell you you're not on that front.

23 THE COURT: Okay.

24 MR. ZIMMERMAN: But if we turn back to Slide 11,
25 there's no doubt -- plaintiffs agree with us that colon

1 cleansing is an important aspect of the invention and they've
2 said that it's a critical aspect of the invention. It's the
3 only one that's characterized that way. That is the
4 fundamental piece that we're dealing with.

5 And then if we go to Slide 12. The prosecution
6 language that plaintiffs pointed out as to why "consisting
7 essentially of" was added. It wasn't added to distinguish
8 other salts, it was added to distinguish other osmotic agents.
9 Those osmotic agents relate to colon cleansing.

10 And so this particular limitation was put in to say
11 what could and couldn't be included from the purposes of colon
12 cleansing. There's no discussion about electrolyte shift,
13 there's no discussion about safety or efficacy. This
14 limitation was added for what's in and what's out for colon
15 cleansing.

16 So we think it's pretty clear from the intrinsic
17 record that that's the basic property we're talking about and
18 the one that should be the focus. But I understand if the
19 Court wants to defer and wait until we have experts, we can do
20 that.

21 Do you have any questions, Your Honor?

22 THE COURT: I don't think so. Anything else you want
23 to say on this issue?

24 MR. ZIMMERMAN: I don't, Your Honor. Thank you.

25 THE COURT: Okay. Do you want to respond,

1 counsel?

2 MR. NOYES: Your Honor, just very briefly.

3 I do think, Your Honor, the positions on what the
4 basic and novel properties are I think are clearly defined.
5 I'm not sure there's an issue that the experts will be unclear.
6 We've told them what our position is, they've clearly told us
7 what their position is today. I think that's just an issue
8 that experts are going to have to hash out.

9 THE COURT: And ultimately we would have an
10 expert, I believe, right? It would be a credibility issue at
11 some point?

12 MR. NOYES: It would be a credibility issue. And
13 again, Your Honor, it's not only the experts, but you'll have
14 testimony from the inventors as well.

15 But again, all of this -- this does feel to me to be
16 an indefiniteness argument, I think that's what they're
17 arguing. And again, we've agreed to defer indefiniteness until
18 after --

19 THE COURT: That's my other concern, then I have to
20 get into that whole issue.

21 But I will tell you generally, here's where my -- I
22 want to take some time to think about it, but as of right now I
23 don't think that it's appropriate for me to decide this issue
24 without there being some discovery, without there being some
25 expert, without you fleshing out -- and I should have said,

1 that includes the inventors themselves because sometimes, you
2 know, that can be helpful as well. But I think that that is
3 the more appropriate way of handling it.

4 I'm not saying that's the way I would do it in every
5 case. But looking at this case and what the issues are and
6 where the disputes are -- because you have a number of disputes
7 on that issue. And no disrespect to anyone, but I'm not a
8 scientist and neither are any of you, and I don't think it's --
9 I don't feel comfortable deciding that issue without expert
10 testimony and deciding ultimately which expert I think is more
11 credible and/or carries the day. And I think that that's the
12 more appropriate time.

13 So as of right now, my intent is not to decide that
14 issue and to just decide the first issue. Given that that --
15 you can be seated, counsel. I am sorry.

16 MR. NOYES: Thank you, Your Honor.

17 THE COURT: Given that that's the case, I'll take some
18 time to go back and look at the transcript from today and go
19 back and read your briefs again, and I will do one of two
20 things: I will either issue a short written opinion or I will
21 get you all on the phone and read a decision -- you don't need
22 to come in, we'll do it by Teams, and I'll do a decision just
23 from the bench depending upon what I decide and how detailed I
24 think it needs to be. Okay?

25 Anything else from the plaintiff today?

1 MS. PIROZZOLO: No, Your Honor.

2 THE COURT: Okay. Anything else from defendant
3 today?

4 MR. ZIMMERMAN: No. Thank you, Your Honor.

5 THE COURT: Okay. We're off the record. We're
6 adjourned for today.

7 (Discussion held off the record.)

8 THE COURT: I'm going to seal the courtroom and ask
9 anyone who's not affiliated with any of the parties who are
10 currently here to please leave the courtroom for a moment so I
11 can discuss with the parties things that would include
12 proprietary information that would not be appropriate to
13 discuss in an open courtroom.

14 And then, counsel, I obviously don't know anyone else
15 in the courtroom, so you can take a look and make sure there
16 are no concerns with whoever else is remaining.

17 MR. NOYES: We got the thumbs up.

18 THE COURT: You're good?

19 MR. NOYES: Yes. Those are Braintree representatives,
20 yes.

21 (By order of the Court, the courtroom was sealed.)

22 THE COURT: So we can go off the record for now.

23 (Discussion held off the record.)

24 (By order of the Court, the courtroom was unsealed.)

25 THE COURT: We're adjourned. You can unseal the

1 courtroom.

2 Have a good day, counsel.

3 (Matter adjourned at 12:40 p.m.)

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6 I certify that the foregoing is a correct transcript
7 from the record of proceedings in the above-entitled matter.

8

9 /S/ Sharon Ricci, RMR, CRR
10 Official Court Reporter

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12 October 29, 2024
13 Date

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